OPTIONS FOR RABIES VACCINATION OF DOGS AND CATS IN TEXAS

I. Purpose of the Report

The purpose of this report is to explore the options for rabies vaccination protocols in dogs and cats in Texas which would adequately and appropriately protect the public's health. Six options have been proposed that comply with current statutory law:

1. annual vaccination using any approved vaccine
2. annual vaccination using a vaccine approved for three years (triennial vaccine)
3. vaccination every two years with a triennial vaccine
4. vaccination every three years with a triennial vaccine
5. vaccination according to manufacturer's recommendations
6. initial vaccination with titer check

It is evident that many dogs and cats in Texas are not receiving any rabies vaccinations at all. Pet owners' complete failure to vaccinate their animals presents a serious public health danger; however, total noncompliance cannot be remedied through vaccination protocols but must be addressed through education and enforcement of existing laws. The purpose of this document is to explore options for rabies vaccination protocols; therefore, discussion will focus on vaccination intervals rather than the complete failure to vaccinate pets.

II. Overview of Rabies & Rabies Vaccine

Rabies is a universally fatal disease of mammals, including humans. Aggressive rabies control measures in animals and postexposure treatment in humans have resulted in a low incidence rate of human rabies in the United States. Between 1990 and 2000, there were 32 human deaths due to rabies in this country. Of those, 24 cases were the result of variants of the rabies virus commonly found in bats; six were exposed to rabies outside of the United States and died of rabies variants not found in this country. The remaining two cases lived in Texas and contracted the variant of rabies that infects domestic dogs and coyotes. Exactly how these last two people were exposed to rabies could not be determined.

Life-saving treatment is available for people and is effective if given soon after exposure to the rabies virus. Once clinical signs develop, treatment is no longer effective and the outcome is death. The cost for rabies biologicals is significant and ranges from $900 to $1,400 per person depending on body weight, exclusive of physician charges and associated costs such as transportation and time away from work.[a]

Between 1998 and 2000, an average of 573 people annually received rabies biologicals from the Texas Department of Health due to exposure to potentially rabid dogs and cats. The quantity of rabies biologicals dispensed through private sources, such as hospitals, is unknown.

There are many types of rabies viruses, each of which is called a variant. Each individual variant of rabies will perpetuate itself in nature through repeated transmissions only in the mammalian species for which it is adapted. Although "spillover" of the particular variant might occur in an alternate species (such as the gray fox rabies variant in a cow), spillover rabies usually presents as a single rabies case and does not continue to spread.

Texas is the only state in the U.S. in which rabies outbreaks due to the domestic dog/coyote variant of the virus have occurred in recent years. Throughout history, the canine variants of the rabies virus have caused millions of deaths worldwide. The canine variants are regarded as especially dangerous because they are readily transmitted amongst and between wild and domestic canines (such as coyotes and dogs) and, subsequently, to people due to their close association with pet dogs. Texas' Oral Rabies Vaccination Program has curbed the outbreak of the domestic dog/coyote variant in Texas with only an occasional case occurring near the US-Mexico border.

Rabid domestic animals are far more likely to expose humans to rabies than are rabid wild animals. For every 100 dogs and cats that are tested for rabies in Texas and found to either have positive or inconclusive results, 170 people are potentially exposed while only 16 people are potentially exposed for every 100 terrestrial wild animals that tests positive or inconclusive.

[a] Unpublished data – Texas Department of Health, Zoonosis Control Division

The number of laboratory-confirmed rabid dogs and cats in Texas is contained in Figure 1. According to figures from the American Veterinary Medical Association, over 60% of Texas households own companion animals, with an estimated 5.9 million dogs and 6.6 million cats residing in the state.

Year	Dogs	Cats	Wildlife
1996	15	10	308
1997	11	2	241
1998	15	8	258
1999	13	21	346
2000	19	17	774

Figure 1. Laboratory-confirmed cases of rabies in Texas

During the 1950s, two concurrent events contributed to a dramatic reduction in the number of rabid dogs in the United States. First, a safe, effective rabies vaccine for dogs was developed. Second, cities began enacting more stringent animal control laws, including the removal of stray dogs. The number of confirmed cases of rabies in dogs in the United States was reduced from 6,648 in 1941 to 160 in 1989, despite an increase in the number of confirmed cases of rabies in wildlife.

Two general types of rabies vaccines for dogs and cats are currently available in the United States: vaccines that are approved for use on an annual basis and vaccines that are approved for use on a triennial basis. Advances in technology are occurring which may result in new vaccines being introduced.

The United States Department of Agriculture (USDA), based upon Title 9 CFR §113.209, governs preparation and testing of rabies vaccines. The USDA requires that rabies vaccines be tested using challenge trials that include a minimum of 25 vaccinated animals and 10 unvaccinated controls. The animals in the vaccine group receive one dose of rabies vaccine. During the first year, all test animals receive five blood tests for neutralizing antibody titers to the rabies virus. For duration of immunity trials of more than one year, the test animals are monitored serologically every six months for the remaining time of the trial. At the end of the trial period, the vaccinates and the controls are both challenged by injection with virulent rabies virus into the masseter (jaw) muscle using USDA-provided virus of the New York City dog strain. The challenged animals are then observed for 90 days. The brains of test animals that die following challenge are examined for evidence of rabies infection using fluorescent antibody testing. A successful challenge trial requires that 80% of the controls die of rabies and 87% of the vaccinates survive for 90 days.

III. Current Recommendations & Laws Regarding Rabies Vaccination

The Compendium of Animal Rabies Prevention and Control sets forth the recommendations of the National Association of State Public Health Veterinarians for rabies control in the United States. The Compendium recommends that a triennial vaccine be administered to dogs and cats in accordance with the manufacturer's specifications. The product labels for the triennial rabies vaccines currently on the market call for the first vaccination to be administered at three months of age with a booster given one year later and then every three years thereafter. The product labels for most of the annual rabies vaccines states that the animal should be vaccinated at three months of age and annually thereafter. One manufacturer's annual rabies vaccine for cats is approved by the USDA for use in animals as young as eight weeks of age.

Rabies vaccination laws for dogs and cats vary widely among the states with some states following the Compendium's recommendations and others opting for different protocols due to the unique characteristics of their states. Current state rabies laws are as follows (Figure 2):

- 33 states permit vaccinating according to the Rabies Compendium;
- 10 states allow local jurisdiction for rabies vaccination intervals;
- 2 states require a rabies vaccination every two years;
- 5 states require rabies vaccination each year.

Texas state law allows only veterinarians to administer rabies vaccinations.[b] Using this law as its basis, the Texas Department of Health has administrative rules which require that dogs and cats be vaccinated by four months of age and annually thereafter.[c] These administrative rules require that a vaccine with a three-year duration of immunity be used in dogs. This requirement for dogs was instituted in 1996 after then Governor Ann Richards declared rabies to be a public health emergency in Texas. The vaccine to be used in cats is not specified in the administrative rules and, therefore, can be either the one-year or the three-year product.

[b] Texas Health and Safety Code, Chapter 826, Section 826.023
[c] Texas Rabies Control and Eradication, Section 169.29a

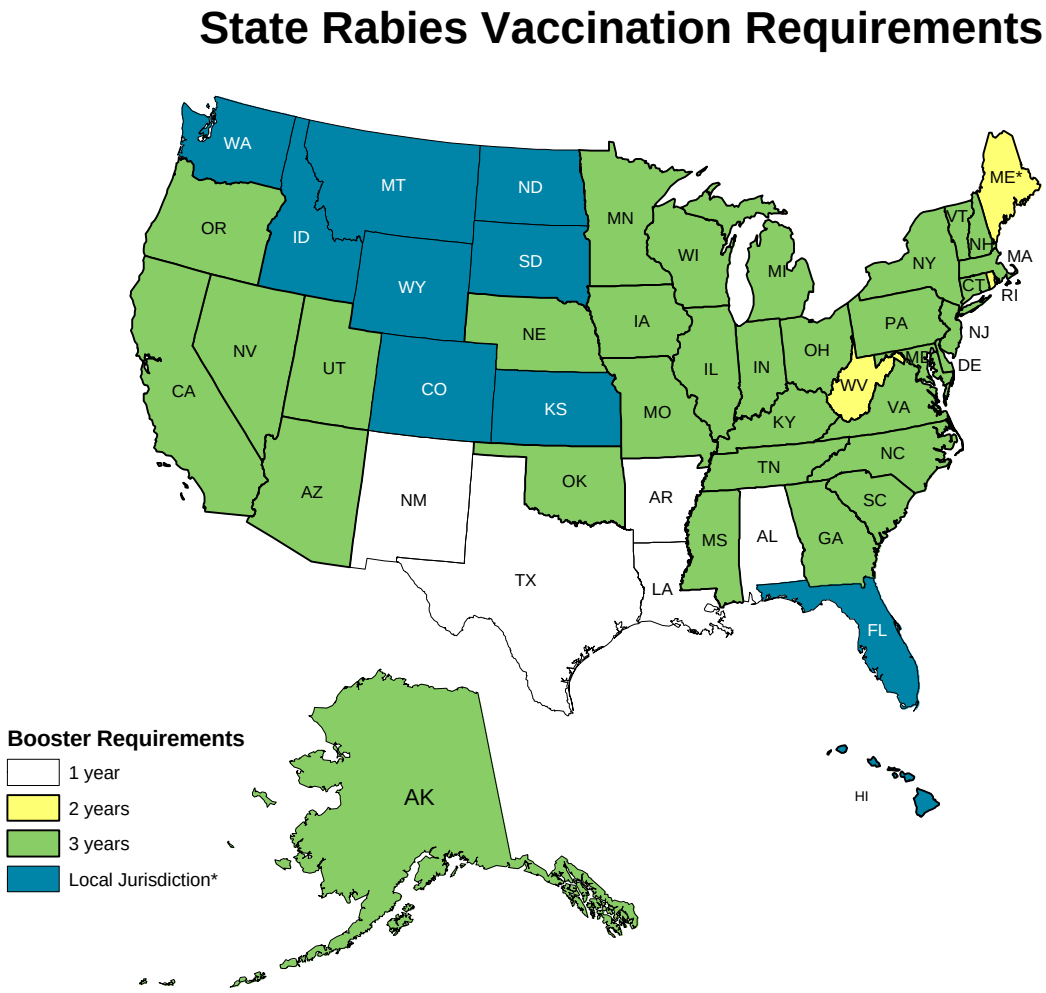

Figure 2.

* State law delegates vaccination interval protocols to local-level governments

IV. Vaccination Efficacy

One common concern about vaccine efficacy is the actual duration of immunity conferred by triennial vaccines. In other words, manufacturers of triennial vaccines have satisfied USDA requirements to demonstrate that the vaccine confers immunity for at least three years, but how much longer than three years does the protection last? Vaccine manufacturers consider duration of immunity studies to be proprietary information. While manufacturers are required to provide test results to the USDA, neither they nor the USDA are required to reveal those results to the public, and they opt not to do so.

Very few studies on the duration of immunity of rabies vaccines can be found in the literature, with none that demonstrate duration of immunity for vaccines currently used in the United States. A vaccine manufacturer, Merial Inc, performed the longest challenge trial by testing cats at 44 months. The vaccine was 100% effective in these cats. In another study, Dr. Ronald Schultz of the Madison College of Veterinary Medicine at the University of Wisconsin found antibodies to rabies in dogs at seven years postvaccination, but he did not perform rabies challenge studies.[d] The scientific consensus is that data are not available to validate protection beyond three years.

[d] Data courtesy of Dr. Schultz, University of Wisconsin - College of Veterinary Medicine

V. Vaccination Compliance Rates

Human behavior is the most difficult part of evaluating vaccination policies. Public health officials in most states do not know the vaccination rates for dogs and cats in their states. There are a number of obstacles to obtaining that data. When conducting surveys, it is difficult to validate the owner's ability to recall if and when the pet was vaccinated and to ensure honest responses in these surveys. As an example of survey accuracy, the American Society for Microbiology conducted a national telephone survey of 1,021 adults asking if they washed their hands after using public restrooms. They also placed observers in public restrooms in five major metropolitan areas who observed the behavior of 7,836 men and women. Ninety-five percent of those interviewed said they washed their hands; however, only 67% were actually observed washing their hands.

People may be even more likely to provide inaccurate information about vaccinations required by law, especially if they are concerned about repercussions from enforcement. Connecticut researchers randomly interviewed 1,810 households in 1993. The owners reported that 93% of dogs and 80% of cats were vaccinated against rabies. A similar study in Maine claims that 96% of dogs and 79% of cats had been vaccinated within the previous two years. Using a different method (estimation of the total number of dogs and cats compared to the number reported vaccinated by veterinarians), data from Alabama indicate that approximately 28% of cats and 60% of dogs are vaccinated against rabies in Alabama each year.[e] It is unknown whether the difference between Alabama and the New England states is because of lack of recall and/or dishonest responses on the part of the owner or if a difference in compliance truly exists between the populations.

The Texas Department of Health reviewed case investigations involving 198 cats and 1,233 dogs in Texas which had been exposed to potentially rabid animals during the years 1998 through 2000. The analysis revealed that 19% of the animals had received a rabies vaccination in the past but were delinquent at the time of exposure (Figure 3). For those dogs and cats which were delinquent in receiving their rabies vaccinations, the average length of time between the animal's last vaccination and its exposure to a rabid animal was 19 months (i.e., it was 7 months overdue for its annual booster).

Animal	Never Vaccinated	Currently Vaccinated	Previously vaccinated but not current
Dog	29%	51%	20%
Cat	59%	25%	16%
Dog & Cat	33%	48%	19%

Figure 3. Rabies vaccination status of dogs and cats potentially exposed to a rabid animal, 1998-2000

One of the arguments for yearly vaccination of dogs and cats is that owner compliance will be higher than with triennial vaccination because annual events present an easily recognized and remembered routine. Also, most veterinarians mail reminders to clients to prompt them to obtain their pets' rabies vaccinations. One of the concerns about vaccinations given every three years is that, in today's mobile society, clients will move and not receive mailed reminders, the result being that the rabies vaccination will not be obtained or will be delinquent. If the client obtains preventive care other than rabies (such as other vaccinations, heartworm testing and prevention, or dental prophylaxis), these reminders are sent on a more frequent basis. Therefore, the concern about owners failing to receive rabies reminders focuses primarily on the owners who obtain only rabies vaccinations for the pet without other preventive care.

[e] unpublished data provided by Bill Johnston, DVM, DACVPM, of the Alabama Department of Public Health

In an attempt to see if a difference in delinquency rates exists between states requiring rabies vaccination each year (one-year states) and states requiring rabies vaccinations every three years (three-year states), the Texas Department of Health obtained data from Banfield Corp., which owns VetSmart. Banfield Corp. provided data from seven states where they have clinics (Texas and Florida which are one-year states and Arizona, California, Illinois, North Carolina, and South Carolina which are three-year states). The data contained the vaccination status of 1,600,000 dogs and 582,000 cats based on a form completed by the veterinarian indicating if the vaccine was administered early, late, or on time. When looking at the data for the people who elected to have their pets receive rabies vaccination only and no other preventive care, comparison of the one-year states and the three-year states demonstrates no difference in the delinquency rates.

VI. Potential Adverse Effects of the Rabies Vaccination

In the early 1990s, veterinary oncologists and pathologists noted an increase in the occurrence of tumors in cats known as sarcomas. While the exact cause of this increase in sarcomas has not been determined, evidence indicates a causal relationship between vaccination against rabies and/or feline leukemia virus and the development of these sarcomas at the site of vaccination. These retrospective studies have also demonstrated that vaccination-site sarcomas tend to occur in younger cats and are less responsive to therapy than sarcomas not associated with vaccination sites. Currently, insufficient data exist to assess the relative risk of administering a particular vaccine or antigen to an individual cat, but ongoing research is attempting to define the scope and incidence of the problem and determine causal and prognostic factors relating to the disorder. The true incidence of vaccine-associated sarcomas in cats is unknown but attempts to quantify its occurrence range from 1 case/10,000 cats to 10 cases/10,000 cats.

Although most of the discussion about adverse consequences of vaccine administration has been focused on cats, some evidence associates detrimental effects with vaccine administration in dogs. In a case-control study at the University of Pennsylvania, researchers reached the conclusion that a marked difference existed in the frequency of immune-mediated hemolytic anemia in dogs which had been vaccinated versus the control group.

The veterinary profession has begun to question some previously held beliefs regarding vaccination practices. Increasing numbers of veterinarians and professors at colleges of veterinary medicine in the United States are advocating that vaccination is a medical procedure that should be undertaken with the same thoughtful consideration as any other medical procedure in veterinary practice, to be performed after careful assessment of the needs of the patient with consideration given to the medical importance and zoonotic potential of the infectious agent and the patient's risk of exposure.

VII. Rabies Titers

One alternative to requiring regularly occurring rabies boosters in dogs and cats would be an initial series of rabies vaccinations with the option, in lieu of boosters, to periodically perform a blood test to determine if the animal has a titer against the rabies virus. If the animal had an adequate titer, no booster vaccination would be necessary; if the animal had no titer or a low titer, a booster would be required. Rabies prevention in humans presents a model for this concept in that it is recommended that people who are at high risk for exposure to rabies (such as veterinarians, animal control officers, and spelunkers) receive preexposure rabies vaccinations. Rather than receiving boosters at regular intervals, the person should have his or her titer tested and receive a booster only if the titer has dropped below acceptable levels.

At least two reasons exist for why blood testing is not an acceptable substitute for rabies vaccination in animals. First, most veterinary immunologists agree that rabies titers provide a sketch of the animal's past exposure to the rabies virus but do not indicate a level of protection. A titer of 0.5 IU/ml is considered acceptable, but it is not known whether it is protective. Studies have demonstrated that dogs with low titers and even no titers were protected when injected with rabies virus. This may be due to the fact that a titer measures only one of the two types of immunity. In addition to the humoral, or antibody, response measured by titer tests, rabies vaccine produces cell-mediated immunity. This cell-mediated response is important in protecting against rabies, but no commercial assay is currently available that offers an economical, accurate, and rapid assessment.

The second reason that human recommendations cannot be extrapolated to animals lies in the chain of events that occurs after a human, dog, or cat is exposed to rabies. Typically when a human is bitten by an animal, it is determined whether or not the animal has rabies. If the animal is rabid, the person undergoes a series of postexposure treatments to prevent rabies from developing. Postexposure treatment is recommended regardless of whether the individual had preexposure vaccinations or an acceptable titer. In contrast to humans, when a dog or cat is bitten, the owner is often not aware that a bite occurred or that the biting animal was rabid, and no postexposure treatment is administered.

VIII. Summary

For reasons cited in this document, determining a rabies titer in lieu of a vaccination is not an acceptable means of protecting the public's health.

Historical use of the annual and triennial rabies vaccines has shown them both to be effective in preventing rabies in dogs and cats. A paucity of scientific data exists to demonstrate a clear public health benefit of a one-year vaccination protocol versus a three-year vaccination protocol.

The issue of vaccination frequency is highly polarized with various groups advocating a preferred interval. The Texas Department of Health will seek stakeholder input in the form of comments made both in writing and at public meetings. Upon the conclusion of the comment period, the Texas Department of Health will review the scientific data in combination with the input given by stakeholders to determine if the current Rules for Rabies Control and Eradication adequately and appropriately safeguard the public's health.

The fact that approximately 33% of the dogs and cats in Texas have never received a rabies vaccination and 19% are overdue for their rabies vaccination represents a serious public health danger. Failure to comply with rabies vaccination regulations must be addressed through education and enforcement of existing laws.

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